

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
29 March 2001 (29.03.2001)

PCT

(10) International Publication Number
WO 01/21243 A1

(51) International Patent Classification⁷: A61M 25/092,
25/01

(21) International Application Number: PCT/SE00/01816

(22) International Filing Date:
19 September 2000 (19.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9903430-8 22 September 1999 (22.09.1999) SE

(71) Applicant (for all designated States except US): ST. JUDE
MEDICAL AB [SE/SE]; S-175 84 Järfälla (SE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): HILL, Rolf [SE/SE];

Gösvägen 8, S-175 55 Järfälla (SE). JOHANSSON,
Göran [SE/SE]; Evalundsgatan 1b, S-151 45 Södertälje
(SE). WARGELIUS, Maria [SE/SE]; Palmbladsvägen 3,
S-112 58 Stockholm (SE). JARL, Per [SE/SE]; Vålber-
gavägen 285, S-175 69 Järfälla (SE).

(74) Common Representative: ST. JUDE MEDICAL AB;
Patent Dept., S-175 84 Järfälla (SE).

(81) Designated State (national): US.

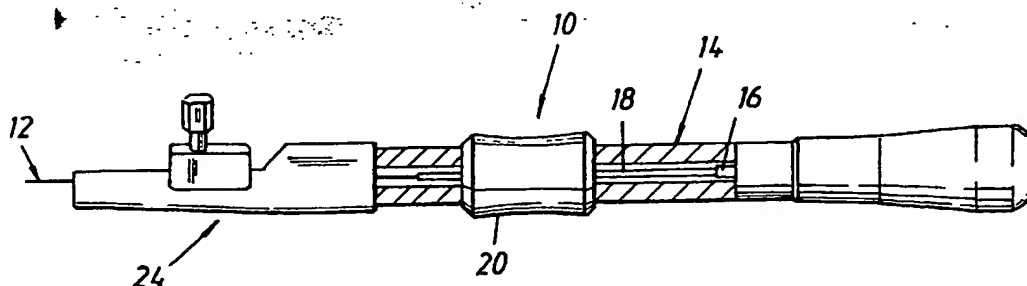
(84) Designated States (regional): European patent (AT, BE,
CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC,
NL, PT, SE).

Published:

— With international search report.

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: A DEVICE FOR MANIPULATING A STYLET UNIT



(57) Abstract: A device for manipulating a stylet unit for positioning of an electrode cable in a body cavity. The device comprises a handle supporting at a distal portion thereof a rotatable bracket member. A slide member carrying a screw for fixation of a proximal contact element of the electrode cable is displaceably mounted in the bracket member so as to be adjustable to variations of length of a central lumen of the electrode cable into which the stylet unit is to be inserted.

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A DEVICE FOR MANIPULATING A STYLET UNIT

Background of the invention

1. FIELD OF THE INVENTION

The present invention relates in general to a device for manipulating a stylet for positioning an electrode cable in a body cavity, such as a human heart. More particularly, the present invention relates to a device for manipulating a stylet unit of the type consisting of a stylet sleeve and a guide wire located within said sleeve. The distal end portion of the inner guide wire is pre-shaped into a curved configuration so that when it is freely exposed from the distal end portion of the associated flexible, but stiffer stylet sleeve by performing a relative displacement between the latter and the guide wire, the free distal end portion of the guide wire will be capable of bending the distal end portion of the electrode cable into a desired curved shape. In this manner, the tip of the electrode cable may be bent between a substantially straight configuration to a substantially J-shaped configuration in order to locate and fixate the tip of the electrode cable at a suitable site in the heart.

2. DESCRIPTION OF THE PRIOR ART

US-A-5 170 787 discloses a device for manipulating a stylet unit of the kind referred to above for *in vivo* positioning of an electrode cable, wherein said device comprises a handle having a first handle member and a second handle member attached to one another for mutual movements thereof, one of said handle members being connected to a proximal end portion of one of said stylet sleeve and guide wire, while the other of said handle members being connected to a proximal end portion of the other of said stylet sleeve and guide wire; and a means attached to a distal end portion of one of said first and second handle

members for fixation of a proximal contact element of the electrode cable to said one of the first and second handle members. Such a prior art device normally operates smoothly and flawlessly with electrode cables having substantially the same length of the central lumen into which the stylet unit is to be inserted. Thus, in order to obtain proper function of the device, e.g. to ensure accurate control of the electrode tip while positioning the same in e.g. a heart, it is important that the distal tip of the guide wire always reaches the bottom end of the lumen, while the proximal contact element of the electrode cable is fixated to its associated handle member of the device. Although the overall outer length of the electrode cables may be substantially identical, the length of their inner central lumen may vary in dependence of the actual electrode tip design being used, e.g. active (screw-in) or passive fixation (fins or tines). Also manufacturing tolerances of some models of the electrode cables may vary within the range $\pm 1,3$ cm. In the preferred embodiment of the stylet manipulating device of US-A-5 170 787, the distance between the distal end of the guide wire and the point of fixation of the proximal element of the electrode cable to the associated one of the handle members should be a fixed distance, i.e. said associated handle member should be a stationary handle member to which the guide wire is attached, and the other handle member should be a displaceable handle member to which the stylet sleeve is attached. Such a previously known fixed length-manipulating device is therefore not suitable for obtaining accurate handling of the tip of the electrode cables having various lengths of the lumen thereof.

In order to modify existing stylet manipulating devices of the above-mentioned type so as to accommodate lumen length variations and manufacturing tolerances, it has been suggested (see "846/Research Disclosure. July 1998, publication 41106") to provide a set of adapters of various lengths (Figs. 2 and 3) which are detachably mountable to one and the same handle unit. These adapters are made to fit various predetermined electrode lumen lengths. Furthermore, Fig. 4 of said publication "41106" indicates the use of a telescopic adapter assembly to

accommodate lumen length variations by means of one single handle/stylet unit. Such a telescopic assembly requires rather complicated and expensive structural means in order to obtain accurate and stable length adjustments and to prevent mutual rotation of the telescopic elements.

Summary of the invention

It is an object of the present invention to eliminate the aforementioned shortcomings of the prior art devices and to provide a simplified stylet manipulating device, which comprises one single stylet/handle unit which can be used for manipulations of electrode cables having various lumen lengths.

This object is achieved by a device having the characterizing features as set forth in the following claim 1.

Further features and advantages of the device of the present invention will be apparent from the following detailed description of the invention in conjunction with the accompanying drawings.

Brief description of the drawings

Fig. 1 is a side view of a first embodiment of a stylet manipulating device of the present invention;

Fig. 2 is an exploded perspective view of a bracket and a slidable fixation means of the device in Fig. 1;

Fig. 3 is a perspective view of the bracket and the slidable fixation means in Fig. 2 in the assembled state; and

Fig. 4 is an exploded perspective view of an alternative embodiment of a bracket and a slide assembly of a stylet-manipulating device of the present invention.

Description of preferred embodiments

As shown in Fig. 1, 10 generally denotes a device of the present invention for manipulating a stylet unit 12 consisting of a tubular stylet sleeve and a guide wire located within the sleeve, for positioning of an electrode cable in a body cavity, such as a heart. The device 10 comprises a handle 14 to be hand-held by an operator during implantation of the electrode cable. The proximal or rear end of the guide wire is fixated in the rear part of the handle 14 and extends forwardly through a first stationary guide tube 16 and through a second guide tube 18 which is attached to a stylet sleeve manoeuvring element 20 and telescopically slidable within the first guide tube 16 when the manoeuvring element 20 is pushed back and forth by the thumb and the index finger of the operator. The proximal or rear end of the stylet sleeve is secured to the inside of the second guide tube 16 for movement together therewith. The stylet unit 12, i.e. the stylet sleeve and the guide wire, extends further forwardly through a central passage 22 in a bracket member 24 which is rotatably attached to the distal end portion of the handle 14, and through a passage 26 in a slide member 28 for fixation of a proximal contact element of the electrode cable to be connected to the manipulating device 10.

In a free state, i.e. when the stylet sleeve is retracted rearwardly, the distal end portion (not shown) of the guide wire of the stylet unit 12 has a pre-shaped curved configuration so as to be able to – in a manner known per se – bend the distal end of the electrode cable into a desired curved configuration, such as a J-shape, when the stylet unit 12 is fully inserted to the bottom of the central lumen of the electrode cable.

In order to adapt the manipulating device 10 to electrode cables having various lengths of the central lumen, i.e. to make it possible to adjust the longitudinal position of the fixation of the proximal contact element of the electrode cable to the handle 14, while holding the distal end of the guide wire against the bottom of the electrode lumen, the fixation slide member 28 is longitudinally slidable in the bracket member 24 and securable in a desired position therein. As shown in Figs. 1-3, in the preferred embodiment of the invention the bracket member 24 comprises a proximal base portion 30 which is rotatably attached to the distal end of the handle 14, and a distal shaft portion 31 having a substantially U-shaped cross-section with parallel and inwardly directed flanges 32-34 for guidance of the fixation slide member 28 along the shaft portion 31. The slide member 28 comprises a body portion 36 having on the opposite side walls thereof guide tracks or grooves 38,40, which are formed complementary with the flanges 32,34, respectively, on the shaft portion 31. A threaded bore 41, extending from a top wall of the body portion 36 into the passage 26, is adapted to receive a screw 44 for fixation of the proximal contact element of the electrode cable to the slide member 28. The slide member 28 in its turn is lockable to the shaft portion 31 by means of a locking knob 42 formed integrally with the body portion 36 and spring-biased transversely towards the flange 32 such that one or more lugs (not shown) on the knob 42 may be brought into locking engagement with a toothed rim 45 on the flange 32 at a desired position along the shaft portion 31. The slide member 28 may be released from its locked position by pressing the knob 42 towards the body portion 36.

Instead of having interlocking lugs and teeth, the slide member 28 may be held in a suitable position on the bracket member 24 by frictional engagement between these components, or by a separate lock screw (not shown) clamping the slide member to the shaft portion.

A second embodiment of the bracket and slide member assembly of the manipulating device of the present invention is shown in Fig. 4. In contrast to the first embodiment in Figs. 1-3, the shaft portion 31' of the bracket member 24' has a tubular shape, and a cylindrical slide member 28' fits slidably in the tubular shaft portion 31'. The slide member 28' has a central passage for the penetration of the stylet unit 12, and a widened distal orifice 46 for receiving the proximal contact element of the electrode cable. A screw 44' is adapted to extend radially through an elongate axial slot 48 in the shaft portion 31' and into engagement with a threaded bore 41' in the cylindrical slide member 28' such that the screw 44' is capable of fixating the proximal contact element of an electrode cable in the orifice 46 as well as locking the slide member 28' in a desired position in the shaft portion 31' by expanding flexible parts of the slide member 28' by further tightening of the screw 44'.

Claims

1. A device for manipulating a stylet unit consisting of a stylet sleeve and a guide wire located within said sleeve, for positioning an electrode cable in a body cavity, said device comprising:

a handle having a first handle member and a second handle member attached to one another for mutual movements thereof, one of said handle members being connected to a proximal end portion of one of said stylet sleeve and guide wire, while the other of said handle members being connected to a proximal end portion of the other of said stylet sleeve and guide wire; and

a means attached to a distal portion of one of said first and second handle members for fixation of a proximal contact element of the electrode cable to said one of the first and second handle members, said fixation means being displaceably mounted relative to its associated handle member so as to be adjustable to variations of length of a central elongate lumen of the electrode cable into which the stylet unit is to be inserted,

characterized in that the fixation means comprises a slide member slidably mounted in a single bracket member having a proximal base portion rotatably attached to said associated handle member and a distal shaft portion having a guide track for the slide member, said slide member carrying a locking means for securing the proximal contact element of the electrode cable to the slide member.

2. The device according to Claim 1, characterized in that the shaft portion of the bracket member has a substantially U-shaped cross-section with inwardly directed flanges.
3. The device according to Claim 1, characterized in that the slide member has grooves complementary with the flanges of the bracket shaft portion.
4. The device according to any one of Claims 1-3, characterized in that the slide member is lockable to the bracket member by frictional engagement between the members.
5. The device according to any one of Claims 1-3, characterized in that the slide member is lockable to the bracket member by means of a ratchet mechanism.
6. The device according to Claim 4 or 5, characterized in that the slide member comprises mutually flexible portions adapted to exert transversally directed biasing forces on the bracket shaft portion.
7. The device according to Claim 6, characterized in that one of the flexible portions of the slide member is provided with at least one locking protrusion engageable with ratchet teeth on one of the leg flanges of the bracket shaft portion.
8. The device according to Claim 1, characterized in that the shaft portion of the bracket member is tubular and provided with a longitudinally extending slot for receiving therein the locking means of the slide member which is slidable within the tubular shaft portion.

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Fig. 1

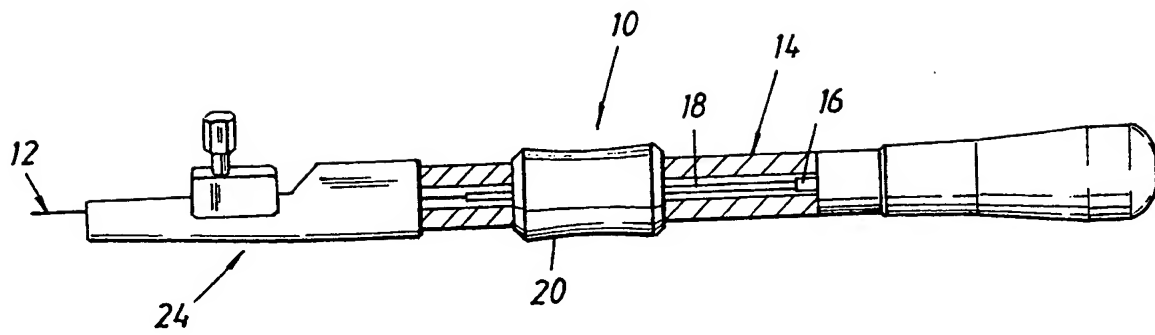
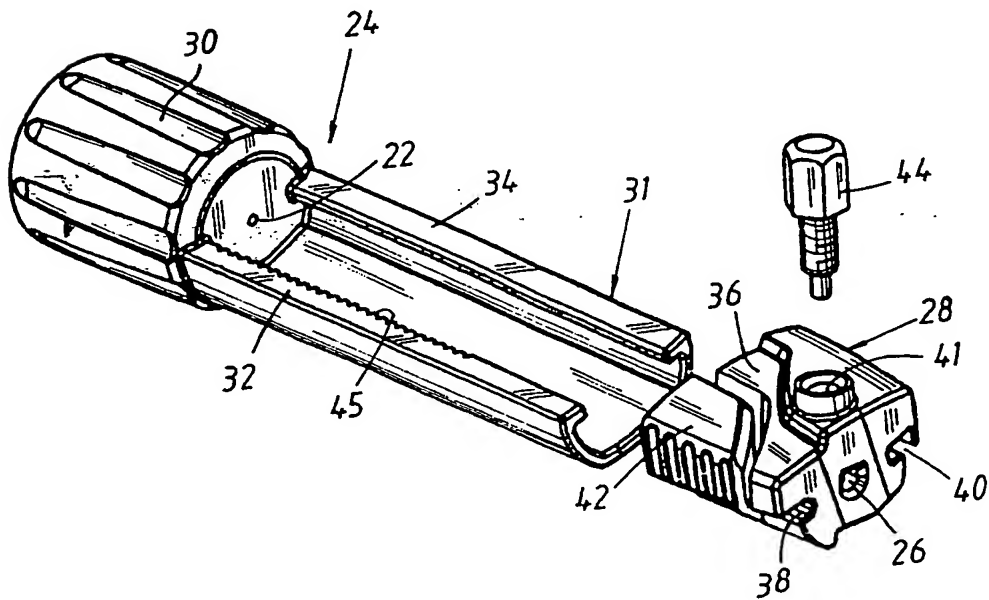


Fig. 2



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Fig. 3

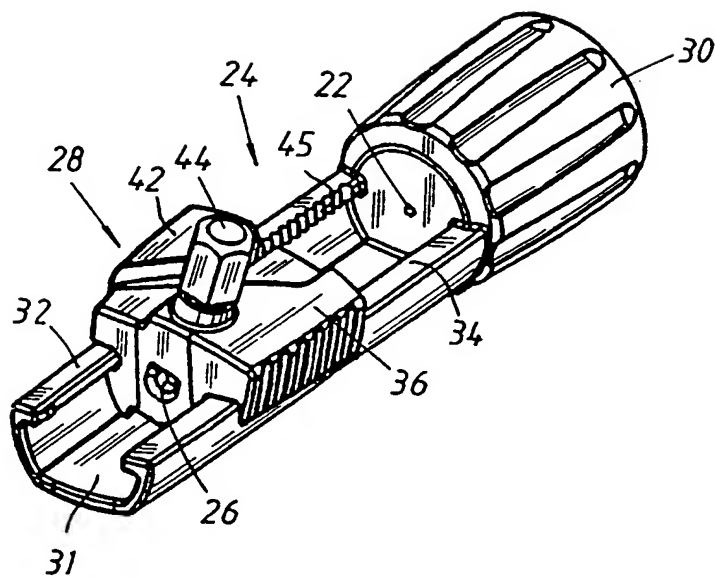
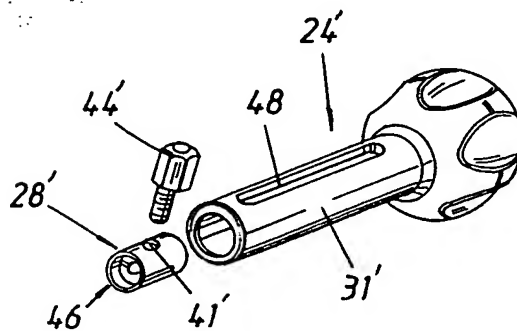


Fig. 4



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/01816

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 25/092, A61M 25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9912600 A1 (THE BOC GROUP PLC), 18 March 1999 (18.03.99), figures 1-2, abstract --	1-8
A	US 4858810 A (M.J. INTLEKOFER ET AL.), 22 August 1989 (22.08.89), figure 1, abstract --	1-8
A	EP 0534747 A1 (COOK INCORPORATED), 31 March 1993 (31.03.93), figure 1, abstract --	1-8
D,A	US 5170787 A (U. LINDEGREN), 15 December 1992 (15.12.92), abstract --	1-8

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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"O" document referring to an oral disclosure, use, exhibition or other means	
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Date of the actual completion of the international search

6 December 2000

Date of mailing of the international search report

08-12-2000

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM

Authorized officer

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/01816

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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02/11/00

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